Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

VA/DoD clinical practice guideline for diagnosis and treatment of low back pain.

Bibliographic Source(s)

Diagnosis and Treatment of Low Back Pain Work Group. VA/DoD clinical practice guideline for diagnosis and management of low back pain. Version 2.0. Washington (DC): Department of Veterans Affairs, Department of Defense; 2017 Sep. 110 p. [142 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Veterans Health Administration, Department of Defense. Clinical practice guideline for the management of low back pain or sciatica in the primary care setting. Washington (DC): Department of Veterans Affairs (U.S.); 1999 May. Various p. [216 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

NEATS Assessment

National Guideline Clearinghouse (NGC) has assessed this guideline's adherence to standards of trustworthiness, derived from the Institute of Medicine's report Clinical Practice Guidelines We Can Trust.

= Poor = Fair = Good = Very Good = Excellent

Assessment	Standard of Trustworthiness
YES	Disclosure of Guideline Funding Source
	Disclosure and Management of Financial Conflict of Interests
	Guideline Development Group Composition

YES	Multidisciplinary Group
YES	Methodologist Involvement
▮▮▮▮▮	Patient and Public Perspectives
	Use of a Systematic Review of Evidence
▮▮▮▮▮	Search Strategy
▮▮▮▮▮	Study Selection
▮▮▮▮▮	Synthesis of Evidence
	Evidence Foundations for and Rating Strength of Recommendations
▮▮▮▮▮	Grading the Quality or Strength of Evidence
▮▮▮▮▮	Benefits and Harms of Recommendations
▮▮▮▮▮	Evidence Summary Supporting Recommendations
▮▮▮▮▮	Rating the Strength of Recommendations
▮▮▮▮▮	**Specific and Unambiguous Articulation of Recommendations**
▮▮▮▮▮	**External Review**
▮▮▮▮▮	**Updating**

Recommendations

Major Recommendations

Note from the Department of Veterans Affairs and the Department of Defense (VA/DoD) and the National Guideline Clearinghouse (NGC): The recommendations for the diagnosis and treatment of low back pain are organized into 7 sections (A-G below) and 2 modules with 2 algorithms. The accompanying recommendations are provided below. See the original guideline document for the algorithms and evidence tables associated with selected recommendations, including level and quality of evidence, strength of recommendation, and supporting evidence citations.

The strength of recommendation grading (Strong For, Weak For, Strong Against, Weak Against) and recommendation categories (Reviewed, Not reviewed, New-added, New-replaced, Not changed, Amended, Deleted) are defined at the end of the "Major Recommendations" field.

A. Diagnostic Approach

> For patients with low back pain, the Work Group recommends that clinicians conduct a history and physical examination, that should include identifying and evaluating neurologic deficits (e.g., radiculopathy, neurogenic claudication), red flag symptoms associated with serious underlying pathology (e.g., malignancy, fracture, infection), and psychosocial factors. (Strong For; Reviewed, Amended)

For patients with low back pain, the Work Group suggests performing a mental health screening as part of the low back pain evaluation and taking results into consideration during selection of treatment. (Weak For; Reviewed, New-replaced)

For patients with acute axial low back pain (i.e., localized, non-radiating), the Work Group recommends against routinely obtaining imaging studies or invasive diagnostic tests. (Strong Against; Reviewed, Amended)

For patients with low back pain, the Work Group recommends diagnostic imaging and appropriate laboratory testing when neurologic deficits are serious or progressive or when red flag symptoms are present. (Strong For; Reviewed, Amended)

For patients with low back pain greater than one month who have not improved or responded to initial treatments, there is inconclusive evidence to recommend for or against any diagnostic imaging. (Not Applicable; Reviewed, New-added)

B. Education and Self-care

For patients with chronic low back pain, the Work Group recommends providing evidence-based information with regard to their expected course, advising patients to remain active, and providing information about self-care options. (Strong For; Reviewed, Amended)

For patients with chronic low back pain, the Work Group suggests adding a structured education component, including pain neurophysiology, as part of a multicomponent self-management intervention. (Weak For; Reviewed, New-added)

C. Non-pharmacologic and Non-invasive Therapy

For patients with chronic low back pain, the Work Group recommends cognitive behavioral therapy. (Strong For; Reviewed, New-replaced)

For patients with chronic low back pain, the Work Group suggests mindfulness-based stress reduction. (Weak For; Reviewed, New-replaced)

For patients with acute low back pain, there is insufficient evidence to support the use of specific clinician-directed exercise. (Not Applicable; Reviewed, New-replaced)

For patients with chronic low back pain, the Work Group suggests offering clinician-directed exercises. (Weak For; Reviewed, New-replaced)

For patients with acute or chronic low back pain, the Work Group suggests offering spinal mobilization/manipulation as part of a multimodal program. (Weak For; Reviewed, New-replaced)

For patients with acute low back pain, there is insufficient evidence to support the use of acupuncture. (Not Applicable; Reviewed, New-replaced)

For patients with chronic low back pain, the Work Group suggests offering acupuncture. (Weak For; Reviewed, New-replaced)

For acute or chronic low back pain, there is insufficient evidence for or against the use of lumbar supports. (Not Applicable; Reviewed, Amended)

For patients with chronic low back pain, the Work Group suggests offering an exercise program, which may include Pilates, yoga, and tai chi. (Weak For; Reviewed, New-replaced)

For patients with low back pain, there is insufficient evidence to support the use of ultrasound. (Not Applicable; Reviewed, New-added)

For patients with low back pain, there is inconclusive evidence to support the use of transcutaneous electrical nerve stimulation (TENS). (Not Applicable; Reviewed, New-added)

For patients with low back pain, there is insufficient evidence to support the use of lumbar traction. (Not Applicable; Reviewed, New-added)

For patients with low back pain, there is insufficient evidence to support the use of electrical muscle stimulation. (Not Applicable; Reviewed, New-added)

D. Pharmacologic Therapy

For patients with acute or chronic low back pain, the Work Group recommends treating with nonsteroidal anti-inflammatory drugs, with consideration of patient-specific risks. (Strong For; Reviewed, Amended)

For patients with chronic low back pain, the Work Group suggests offering treatment with duloxetine, with consideration of patient-specific risks. (Weak For; Reviewed, New-added)
For patients with acute low back pain or acute exacerbations of chronic low back pain, the Work Group suggests offering a non-benzodiazepine muscle relaxant for short-term use. (Weak For; Reviewed, New-added)
For patients with chronic low back pain, the Work Group suggests against offering a non-benzodiazepine muscle relaxant. (Weak Against; Reviewed, New-added)
For patients with low back pain, the Work Group recommends against benzodiazepines. (Strong Against; Reviewed, New-replaced)
For patients with acute or chronic low back pain with or without radiculopathy, the Work Group recommends against the use of systemic corticosteroids (oral or intramuscular injection). (Strong Against; Reviewed, Amended)
For patients with low back pain, the Work Group recommends against initiating long-term opioid therapy. For patients who are already prescribed long-term opioid therapy, refer to the NGC summary of the VA/DoD clinical practice guideline for opioid therapy for chronic pain. (Strong Against; Reviewed, New-replaced)
For patients with acute low back pain or acute exacerbations of chronic low back pain, there is insufficient evidence to recommend for or against the use of time-limited opioid therapy. Given the significant risks and potential benefits of opioid therapy, patients should be evaluated individually, including consideration of psychosocial risks and alternative non-opioid treatments. Any opioid therapy should be kept to the shortest duration and lowest dose possible. (Not Applicable; Reviewed, New-replaced)
For patients with acute or chronic low back pain, there is insufficient evidence to recommend for or against the use of time-limited (less than seven days) acetaminophen therapy. (Not Applicable; Reviewed, New-replaced)
For patients with chronic low back pain, the Work Group recommend against the chronic use of oral acetaminophen. (Strong Against; Reviewed, New-replaced)
For the treatment of acute or chronic low back pain, including patients with both radicular and non-radicular low back pain, there is insufficient evidence to recommend for or against the use of antiepileptics including gabapentin and pregabalin. (Not Applicable; Reviewed, New-replaced)
For the treatment of low back pain, there is insufficient evidence to recommend for or against the use of topical preparations. (Not Applicable; Reviewed, New-added)

E. Dietary Supplements

For the treatment of low back pain, there is insufficient evidence to recommend for or against nutritional, herbal, and homeopathic supplements. (Not Applicable; Reviewed, New-added)

F. Non-surgical Invasive Therapy

For the long-term reduction of radicular low back pain, non-radicular low back pain, or spinal stenosis, we recommend against offering spinal epidural steroid injections. (Strong against; Reviewed, New-added)
For the very short-term effect (less than or equal to two weeks) of reduction of radicular low back pain, we suggest offering epidural steroid injection. (Weak for; Reviewed, New-added)
For the treatment of low back pain, we suggest against offering intra-articular facet joint steroid injections. (Weak against; Reviewed, New-added)
For patients with low back pain, there is inconclusive evidence to recommend for or against medial branch blocks and radiofrequency ablative denervation. (Not applicable; Reviewed, New-added)

G. Team Approach to Treatment of Chronic Low Back Pain

For selected patients with chronic low back pain not satisfactorily responding to more limited approaches, we suggest offering a multidisciplinary or interdisciplinary rehabilitation program which should include at least one physical component and at least one other component of the biopsychosocial model (psychological, social, occupational) used in an explicitly coordinated manner.

(Weak for; Reviewed, New-replaced)

Definitions

The relative strength of the recommendation is based on a binary scale, "Strong" or "Weak." A strong recommendation indicates that the Work Group is highly confident that desirable outcomes outweigh undesirable outcomes. If the Work Group is less confident of the balance between desirable and undesirable outcomes, they present a weak recommendation.

Similarly, a recommendation for a therapy or preventive measure indicates that the desirable consequences outweigh the undesirable consequences. A recommendation against a therapy or preventive measure indicates that the undesirable consequences outweigh the desirable consequences.

Occasionally, instances may occur when the Work Group feels there is insufficient evidence to make a recommendation for or against a particular therapy or preventive measure. This can occur when there is an absence of studies on a particular topic that met evidence review inclusion criteria, studies included in the evidence review report conflicting results, or studies included in the evidence review report inconclusive results regarding the desirable and undesirable outcomes.

Using these elements, the grade of each recommendation is presented as part of a continuum:

Strong For (or "The Work Group recommends offering this option …")
Weak For (or "The Work Group suggests offering this option …")
No recommendation for or against (or "There is insufficient evidence …")
Weak Against (or "The Work Group suggests not offering this option …")
Strong Against (or "The Work Group recommends against offering this option …")

Note that weak (For or Against) recommendations may also be termed "Conditional," "Discretionary," or "Qualified." Recommendations may be conditional based upon patient values and preferences, the resources available, or the setting in which the intervention will be implemented. Recommendations may be at the discretion of the patient and clinician or they may be qualified with an explanation about the issues that would lead decisions to vary.

Recommendation Categories and Definitions

For use in the 2017 lower back pain (LBD) clinical practice guideline (CPG), a set of recommendation categories was adapted from those used by the United Kingdom National Institute for Health and Care Excellence (NICE). These categories, along with their corresponding definitions, were used to account for the various ways in which recommendations could have been updated from the 2007 LBD CPG.

Evidence Reviewed*	Recommendation Category*	Definition*
Reviewed	New-added	New recommendation following review of the evidence
	New-replaced	Recommendation from previous CPG that has been carried over to the updated CPG that has been changed following review of the evidence
	Not changed	Recommendation from previous CPG that has been carried forward to the updated CPG where the evidence has been reviewed but the recommendation is not changed
	Amended	Recommendation from the previous CPG that has been carried forward to the updated CPG where the evidence has been reviewed and a minor amendment has been made
	Deleted	Recommendation from the previous CPG that has been removed based on review of the evidence
Not reviewed	Not changed	Recommendation from previous CPG that has been carried forward to the updated CPG, but for which the evidence has not been reviewed
	Amended	Recommendation from the previous CPG that has been carried

Evidence Reviewed*	Recommendation Category*	Definition*
		forward to the updated CPG where the evidence has not been reviewed and a minor amendment has been made
	Deleted	Recommendation from the previous CPG that has been removed because it was deemed out of scope for the updated CPG

*Adapted from the NICE guideline manual (2012) and Garcia et al. (2014).

Clinical Algorithm(s)

The following algorithms are provided in the original guideline document:

Module A: Initial Evaluation of Low Back Pain
Module B: Management of Low Back Pain

Scope

Disease/Condition(s)

Acute, subacute, or chronic axial/non-radiating low back pain

Guideline Category

Diagnosis

Evaluation

Management

Treatment

Clinical Specialty

Chiropractic

Internal Medicine

Neurology

Orthopedic Surgery

Physical Medicine and Rehabilitation

Radiology

Rheumatology

Sports Medicine

Intended Users

Advanced Practice Nurses

Chiropractors

Health Care Providers

Nurses

Pharmacists

Physical Therapists

Physician Assistants

Physicians

Psychologists/Non-physician Behavioral Health Clinicians

Guideline Objective(s)

- To provide healthcare providers with a framework by which to evaluate, treat, and manage the individual needs and preferences of patients with low back pain (LBP)
- To assist healthcare providers in all aspects of patient care, including, but not limited to, diagnosis, treatment, and management
- To improve the patient's health and wellbeing by providing evidence-based guidance to providers who are diagnosing or treating patients with LBP

Target Population

Adults 18 years or older with low back pain (LBP)

Note: This clinical practice guideline (CPG) is not intended for and does not provide recommendations for the diagnosis and treatment of LBP in children or adolescents, or pregnant women.

Interventions and Practices Considered

Diagnosis and Screening

- Medical history
- Physical examination
- Mental health screening
- Diagnostic imaging
- Appropriate laboratory testing

Treatment and Management

- Education and self-care
  - Provision evidence-based information regarding expected course, advising patients to remain active, and providing information about self-care options
  - Multicomponent self management intervention, including a structured education component with pain neurophysiology
- Non-pharmacologic and non-invasive therapy
  - Cognitive behavioral therapy
  - Mindfulness-based stress reduction
  - Clinician-directed exercises
  - Spinal mobilization/manipulation as part of a multimodal program
  - Acupuncture
  - Exercise program (Pilates, yoga, tai chi)
- Pharmacologic therapy
  - Nonsteroidal anti-inflammatory drugs
  - Duloxetine
  - Non-benzodiazepine muscle relaxant

Non-surgical invasive therapy (epidural steroid injection)
Multidisciplinary or interdisciplinary rehabilitation program

Note:

The following were considered but no recommendation was made due to insufficient evidence: lumbar supports; transcutaneous electrical nerve stimulation (TENS); lumbar traction; electrical muscle stimulation; time-limited opioid therapy; time-limited acetaminophen therapy; antiepileptics (gabapentin, pregabalin); topical preparations; nutritional, herbal, and homeopathic supplements; medial branch blocks and radio frequency ablative denervation.
The following were considered but not recommended: routinely obtaining imaging studies or invasive diagnostic tests; benzodiazepines; systemic corticosteroids (oral or intramuscular injection); long-term opioid therapy; chronic use of oral acetaminophen; spinal epidural steroid injections; intra-articular facet joint steroid injections.

Major Outcomes Considered

- Diagnostic accuracy (sensitivity and specificity using a gold standard)
- Influence of a diagnostic test on the choice of treatment or post-treatment outcomes
- Timing of care (wait or recovery time; speed of intervention)
- Pain
- Time to reduction of pain
- Resolution of pain with minimal pharmacotherapy approaches
- Functional status and activities of daily living
- Quality of life
- Disability and work status (including work days lost)
- Reduction in analgesics, healthcare utilization and non-pharmacotherapy treatments
- Reduction in recurrence of low back pain (LBP)
- Patient satisfaction
- Harms

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Searches of Unpublished Data

Description of Methods Used to Collect/Select the Evidence

Developing the Scope and Key Questions

The clinical practice guideline (CPG) Champions, along with the Work Group, were tasked with identifying key questions (KQs) to guide the systematic evidence review of the literature on low back pain (LBP). These questions, which were developed in consultation with the Lewin Team, addressed clinical topics of the highest priority for the Department of Veterans Affairs (VA) and Department of Defense (DoD) populations. The KQs follow the population, intervention, comparison, outcome, timing and setting (PICOTS) framework for evidence questions, as established by the Agency for Healthcare Research and Quality (AHRQ). Table A-1 in the original guideline document provides a brief overview of the PICOTS typology.

The Champions, Work Group, and evidence review team carried out several iterations of this process, each time narrowing the scope of the CPG and the literature review by prioritizing the topics of interest.

Due to resource constraints, all developed KQs were not able to be included in the systematic review (SR). Thus, the Champions and Work Group determined which questions were of highest priority, and those were included in the review. Table A-4 in the original guideline document contains the final set of KQs used to guide the SR for this CPG.

Conducting the Systematic Review

Extensive literature searches using the search terms and strategy included in Appendix H identified 5,691 citations potentially addressing the KQs of interest to this evidence review. Of those, 2,118 were excluded upon title review for clearly not meeting inclusion criteria (e.g., not pertinent to the topic, not published in English, published prior to study inclusion publication date, not a full-length article). Overall, 3,573 abstracts were reviewed with 2,846 of those being excluded for the following reasons: not an SR or clinical study, did not address a KQ of interest to this review, did not enroll a population of interest, or published prior to December 1, 2006. A total of 727 full-length articles were reviewed. Of those, 609 were excluded after a full article review for the following: wrong study design or not addressing a KQ of interest, wrong study population or not reporting chronic pain patients separately, SR superseded by more comprehensive review or relevant studies included in report, no outcomes of interest, or other (e.g., being a duplicate). Reasons for their exclusion are presented in Figure A-1 in the original guideline document.

Criteria for Study Inclusion/Exclusion

General Criteria

Clinical studies or SRs published on or after December 1, 2006 to October 21, 2016. If multiple SRs addressed a key question, the most recent and/or comprehensive review was selected. SRs were supplemented with clinical studies published subsequent to the search dates of the SR.
Studies must have been published in English.
Publication must have been a full clinical study or SR; abstracts alone were not included. Similarly, letters, editorials, and other publications that were not full-length clinical studies were not accepted as evidence.
Studies of diagnostic tests must have provided data on at least 50 patients. Studies of treatments must have reported outcome data on at least 50 patients (and at least 25 per study group) unless otherwise noted (see Key Question Specific Criteria below).
Study must have reported an outcome of interest.
Study must have enrolled a patient population in which at least 80% of patients had LBP and were age 18 years or older. If the percentage was less than 80%, then data must have been reported separately for this patient subgroup. Study must have reported in its abstract that patients had LBP.
For studies of treatments, patients must not have had spondylolisthesis, postoperative LBP, or pregnancy-related LBP.

For each treatment or diagnostic test of each KQ, it was first determined whether any SRs addressed the question. If so, only the most comprehensive SR was included. Studies published after the SR's last search date were also considered. If there was not an SR that addressed the KQ, studies from December 2006 onward that met all the inclusion criteria for that KQ were included.

Key Question Specific Criteria

For studies of accuracy (KQ1a), studies/reviews must have reported both sensitivity and specificity (or sufficient information to calculate both values), and must have used a reference standard that was independent of the index test.
For studies of clinical utility (KQ1b), studies/reviews must have compared two groups of patients: one that received the diagnostic test of interest, and one that did not, in order to measure the influence of the test on treatment choice and/or patient outcomes.
For KQs 2 through 8, reviews must have been SRs directly addressing a KQ, and studies must have randomly assigned patients to different treatments (the comparator could have been a placebo treatment). The minimum follow-up was 12 weeks for effectiveness outcomes, and there was no minimum follow-up for harms outcomes. Harms data were extracted from any studies reporting

effectiveness data beyond 12 weeks follow-up.
For KQ 9, studies/reviews did not have to be randomized, but did have to compare the post-treatment outcomes of patients who had a psychosocial risk factor to the post-treatment outcomes of patients who did not have that psychosocial risk factor but were otherwise similar.

Literature Search Strategy

Bibliographic Database Information

Agency for Healthcare Research and Quality (AHRQ): 2006–September 2016 (U.S. Department of Health & Human Services)
Canadian Agency for Drugs and Technologies in Health (CADTH): 2006–September 2016, (Canadian Agency for Drugs and Technologies in Health)
CINAHL: 2006–September 2016 (EBSCO Host)
Cochrane Library: 2006–September 2016 (John Wiley & Sons, Ltd.)
Embase.com (Includes EMBASE and Medline Records): 2006–September 2016 (Elsevier)
Healthcare Standards (HCS): 2006–September 2016 (ECRI Institute)
National Guideline Clearinghouse (NGC): 2006–September 2016 (AHRQ)
National Institute for Health and Care Excellence (NICE): 2006–September 2016 (National Institute for Health and Care Excellence)
PsycINFO: 2006–September 2016 (OVID Technologies, Inc.)
PubMed (In-process and publisher supplied records): 2006–September 2016 (National Library of Medicine

Additional information on the search strategies, including topic-specific search terms and search strategies can be found in Appendix H in the original guideline document.

Number of Source Documents

Overall, 118 articles addressed one or more of the key questions and were considered as evidence in this review. Table A-4 in the original guideline documents indicates the number of studies that addressed each of the questions. See Figure A-1 in the original guideline document for a study flow diagram.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence Rating and Definitions*

High quality — Further research is very unlikely to change confidence in the estimate of effect.
Moderate quality — Further research is likely to have an important impact on confidence in the estimate of effect and may change the estimate.
Low quality — Further research is very likely to have an important impact on confidence in the estimate of effect and is likely to change the estimate.
Very low quality — Any estimate of effect is very uncertain.

*Guyatt, G. H., Oxman, A. D., Vist, G. E., Kunz, R., Falck-Ytter, Y., Alonso-Coello, P., Schünemann, H. J. & the GRADE Working Group. (2008). GRADE; An emerging consensus on rating quality of evidence and strength of recommendations. *BMJ, 336*, 924-926.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Abstracting and Managing Data

For each study included in the review, the following study level details were abstracted: country, purpose, and quality rating. For previous systematic reviews, the search strategy used, study selection criteria, and overall information about the evidence base, including number of included studies and overall patients enrolled were reported. For all studies, the reviewers abstracted data about characteristics of the included patients and interventions being assessed.

Assessing Individual Studies' Methodological Quality (i.e., Internal Validity or Risk of Bias)

As per the Department of Veterans Affairs/Department of Defense (VA/DoD) *Guidelines for Guidelines* document, risk-of-bias (or study quality) of individual studies and previous systematic reviews was assessed using the U.S. Preventive Services Task Force (USPSTF) method. Each study was assigned a rating of Good, Fair, or Poor based on sets of criteria that vary depending on study design. Detailed lists of criteria and definitions of Good, Fair, or Poor ratings for different study designs appear in Appendix VII of the USPSTF procedure manual .

Because the USPSTF does not have criteria specific for evaluation of prognostic studies, the reviewers rated the quality of prognostic studies using the recently-developed Quality in Prognosis Studies tool. This instrument assesses potential bias related to six domains: study participation, study attrition, prognostic factor measurement, outcome measurement, study confounding, and statistical analysis and reporting.

Data Synthesis

The evidence review team used a narrative approach to synthesizing the evidence for all the Key Questions. As indicated in the VA/DoD *Guidelines for Guidelines* document, the first line of evidence was previous systematic reviews. For questions in which a previous review was available, individual studies that met this review's inclusion criteria were used to supplement or update the previous review. The reviewers considered whether subsequent evidence supports the conclusions reported in the previous review. For questions for which no previous review was available, they summarized the overall findings for the outcomes of interest of the studies that addressed a key question.

Assessing the Overall Quality of the Body of Evidence for an Outcome

The overall quality of the body of evidence supporting the findings for the outcomes of interest in this report was assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system. The GRADE system primarily involves consideration of the following factors: overall study quality (or overall risk of bias or study limitations), consistency of evidence, directness of evidence, and precision of evidence. Given time and resources, other factors such as publication bias may also be considered. For more information on the GRADE system go to the GRADE Working Group Web site at the following link: http://www.gradeworkinggroup.org/ .

The GRADE system rates the overall quality of the evidence as High, Moderate, Low, and Very Low (see the "Rating Scheme for the Strength of the Evidence" field). For instance, a body of evidence that consists of randomized controlled trials (RCTs) automatically starts with a rating of high quality. This rating can be downgraded if some of the RCTs have serious flaws such as lack of blinding of outcome assessors, not reporting concealment of allocation, or high dropout rate. Similarly, the quality can be downgraded or further downgraded if inconsistencies of findings are present or if there is a lack of precision surrounding an outcome's effect size.

Assessing Applicability

When describing the evidence base addressing a Key Question, the reviewers discussed aspects of the included studies, such as characteristics of included patients and treatments being assessed that may make the overall findings of the studies more or less applicable to the population, treatments, or outcomes of interest to this review.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Methods

The current document is an update to the 2007 *Department of Veterans Affairs/Department of Defense (VA/DoD) Low Back Pain (LBP) Clinical Practice Guideline (CPG)*. The methodology used in developing the 2017 LBP CPG follows the VA/DoD *Guideline for Guidelines*, an internal document of the VA and DoD Evidence-Based Practice Working Group (EBPWG). The VA/DoD *Guideline for Guidelines* can be downloaded from http://www.healthquality.va.gov/policy/index.asp (see also the "Availability of Companion Documents" field). This document provides information regarding the process of developing guidelines, including the identification and assembly of the Guideline Champions (Champions) and other subject matter experts from within the VA and DoD, known as the Work Group, and ultimately, the development and submission of an updated LBP CPG. The VA Office of Quality, Safety and Value, in collaboration with the Office of Evidence Based Practice, U.S. Army Medical Command, the proponent for CPGs for the DoD, identified four clinical leaders from the VA and the DoD as Champions for the 2017 LBP CPG.

The Champions and the Work Group for this CPG were charged with developing evidence-based clinical practice recommendations, and writing and publishing a guideline document to be used by providers within the VA and DoD healthcare systems. Specifically, the Champions and the Work Group were responsible for identifying the Key Questions (KQs) – those considered most clinically relevant, important, and interesting with respect to the diagnosis and management of patients with LBP. The Champions and the Work Group also provided direction on inclusion and exclusion criteria for the evidence review and assessed the level and quality of the evidence. The amount of new scientific evidence that had accumulated since the previous version of the CPG was taken into consideration in the identification of the KQs. In addition, the Champions assisted in:

- Identifying appropriate disciplines of individuals to be included as part of the Work Group
- Directing and coordinating the Work Group
- Participating throughout the guideline development and review processes

The Lewin Team, including The Lewin Group, Duty First Consulting, ECRI Institute, and Sigma Health Consulting, LLC, was contracted by the VA and DoD to support the development of this CPG and conduct the evidence review. The first conference call was held in June 2016, with participation from the contracting officer's representative (COR), leaders from the VA Office of Quality, Safety and Value and the DoD Office of Evidence Based Practice, and the Champions. During this call, participants discussed the scope of the guideline initiative, the roles and responsibilities of the Champions, the project timeline, and the approach for developing and prioritizing specific research questions on which to base an SR about the diagnosis and treatment of LBP. The group also identified a list of clinical specialties and areas of expertise that were important and relevant to the diagnosis and treatment of LBP, from which Work Group members were recruited. The specialties and clinical areas of interest included: chiropractic care, integrative medicine, neurology, nursing, pain medicine, pharmacy, physical medicine and rehabilitation, physical therapy, primary care, radiology, and surgery.

The guideline development process for the 2017 LBP CPG update consisted of the following steps:

Formulating and prioritizing evidence questions (KQs)
Conducting the systematic review of the literature
Convening a face-to-face meeting with the CPG Champions and Work Group members
Drafting, revising, and submitting a final CPG about the diagnosis and treatment of LBP to the VA/DoD EBPWG

Appendix A in the original guideline document provides a detailed description of each of these tasks.

Convening the Face-to-face Meeting

In consultation with the COR, the Champions, and the Work Group, the Lewin Team convened a three and a half day face-to-face meeting of the CPG Champions and Work Group members on December 6-9, 2016. These experts were gathered to develop and draft the clinical recommendations for an update to the 2007 LBP CPG. Lewin presented findings from the evidence review of KQs 1-9 in order to facilitate and inform the process.

Under the direction of the Champions, the Work Group members were charged with interpreting the results of the evidence review, and asked to categorize and carry forward recommendations from the 2007 LBP CPG, modifying the recommendations as necessary. The members also developed new clinical practice recommendations not presented in the 2007 LBP CPG, based on the 2016 evidence review. The subject matter experts were divided into three smaller subgroups at this meeting.

As the Work Group members drafted clinical practice recommendations, they also assigned a grade for each recommendation based on a modified Grading of Recommendations Assessment, Development and Evaluation (GRADE) and U.S. Preventive Services Task Force (USPSTF) methodology. Each recommendation was graded by assessing the quality of the overall evidence base, the associated benefits and harms, the variation in values and preferences, and other implications of the recommendation.

In addition to developing recommendations during the face-to-face meeting, the Work Group members also revised the 2007 LBP CPG algorithm to reflect the new and amended recommendations. They discussed the available evidence as well as changes in clinical practice since 2007, as necessary, to update the algorithm.

Grading Recommendations

The Champions and Work Group used the GRADE approach to assess the quality of the evidence base and assign a grade for the strength for each recommendation. The GRADE system uses the following four domains to assess the strength of each recommendation:

Balance of desirable and undesirable outcomes
Confidence in the quality of the evidence
Patient or provider values and preferences
Other implications, as appropriate, e.g.: ï‚i
    Resource use
    Equity
    Acceptability
    Feasibility
    Subgroup considerations

The framework in Table A-6 in the original guideline document ("Evidence to Recommendations Framework") was used by the Work Group to guide discussions on each domain.

The strength of a recommendation is defined as the extent to which one can be confident that the desirable effects of an intervention outweigh its undesirable effects and is based on the framework, which combines the four domains. GRADE methodology does not allow for recommendations to be made based on expert opinion alone. While strong recommendations are usually based on high or moderate confidence in the estimates of effect (quality of the evidence) there may be instances where strong

recommendations are warranted even when the quality of evidence is low. In these types of instances where the balance of desirable and undesirable outcomes and values and preferences played large roles in determining the strength of a recommendation, this is explained in the discussion section for the recommendation.

The GRADE of a recommendation is based on the following elements:

Four decision domains used to determine the strength and direction (described above)
Relative strength (Strong or Weak)
Direction (For or Against)

Reconciling 2007 Clinical Practice Guideline Recommendations

Evidence-based CPGs should be current, which typically requires revisions of previous guidelines based on new evidence or as scheduled, subject to time-based expirations. For example, the USPSTF has a process for refining or otherwise updating its recommendations pertaining to preventive services. Further, the inclusion criteria for the National Guideline Clearinghouse specify that a guideline must have been developed, reviewed, or revised within the past five years.

The 2017 LBP CPG is an update of the 2007 LBP CPG. Thus, the content of the 2017 LBP CPG is reflective of the previous version of the CPG, but modified where necessary to reflect new evidence and new clinical priorities.

The Work Group focused largely on developing new and updated recommendations based on the evidence review conducted for the priority areas addressed by the KQs. In addition to those new and updated recommendations, the Work Group considered the current applicability of other recommendations that were included in the previous 2007 LBP CPG without complete review of the relevant evidence, subject to evolving practice in today's environment.

To indicate which recommendations were developed based on the updated review of the evidence versus recommendations that were carried forward from the 2007 version of the CPG, a set of recommendation categories was adapted from those used by the National Institute for Health and Care Excellence (NICE). These categories, along with their corresponding definitions, were used to account for the various ways in which older recommendations could have been updated. In brief, the categories took into account whether or not the evidence that related to a recommendation was systematically reviewed, the degree to which the recommendation was modified, and the degree to which a recommendation is relevant in the current patient care environment and within the scope of the CPG. Additional information regarding these categories and their definitions can be found in the "Recommendation Categorization" section in the original guideline document. The categories for the recommendations included in the 2017 version of the guideline can be found in the "Major Recommendations" field. The categorizations for each 2007 LBP CPG recommendation can be found in Appendix E in the original guideline document.

In cases where a 2007 LBP CPG recommendation was covered by a 2017 KQ, peer-reviewed literature published since the 2007 LBP CPG was considered along with the evidence base used for the 2007 LBPCPG. Where new literature was considered when assessing the strength of the recommendation, it is referenced in the discussion following the corresponding recommendation, as well as in Appendix C in the original guideline document.

The CPG Work Group recognizes that, while there are practical reasons for incorporating findings from a previous SR, previous recommendations, or recent peer-reviewed publications into an updated CPG, doing so does not involve an original, comprehensive SR and, therefore, may introduce bias.

Drafting and Submitting the Final Clinical Practice Guideline

Following the face-to-face meeting, the Champions and Work Group members were given writing assignments to craft discussion sections to support each of the new recommendations and/or to update discussion sections from the 2007 LBP CPG to support the amended "carried forward" recommendations. The Work Group also considered tables, appendices, and other sections from the 2007 LBP CPG for

inclusion in the update. During this time, the Champions and Work Group also made additional revisions to the algorithm, as necessary.

Rating Scheme for the Strength of the Recommendations

The relative strength of the recommendation is based on a binary scale, "Strong" or "Weak." A strong recommendation indicates that the Work Group is highly confident that desirable outcomes outweigh undesirable outcomes. If the Work Group is less confident of the balance between desirable and undesirable outcomes, they present a weak recommendation.

Similarly, a recommendation for a therapy or preventive measure indicates that the desirable consequences outweigh the undesirable consequences. A recommendation against a therapy or preventive measure indicates that the undesirable consequences outweigh the desirable consequences.

Occasionally, instances may occur when the Work Group feels there is insufficient evidence to make a recommendation for or against a particular therapy or preventive measure. This can occur when there is an absence of studies on a particular topic that met evidence review inclusion criteria, studies included in the evidence review report conflicting results, or studies included in the evidence review report inconclusive results regarding the desirable and undesirable outcomes.

Using these elements, the grade of each recommendation is presented as part of a continuum:

Strong For (or "The Work Group recommends offering this option …")
Weak For (or "The Work Group suggests offering this option …")
No recommendation for or against (or "There is insufficient evidence …")
Weak Against (or "The Work Group suggests not offering this option …")
Strong Against (or "The Work Group recommends against offering this option …")

Note that weak (For or Against) recommendations may also be termed "Conditional," "Discretionary," or "Qualified." Recommendations may be conditional based upon patient values and preferences, the resources available, or the setting in which the intervention will be implemented. Recommendations may be at the discretion of the patient and clinician or they may be qualified with an explanation about the issues that would lead decisions to vary.

Recommendation Categories and Definitions

For use in the 2017 Lower Back Pain (LBD) clinical practice guideline (CPG), a set of recommendation categories was adapted from those used by the United Kingdom National Institute for Health and Care Excellence (NICE). These categories, along with their corresponding definitions, were used to account for the various ways in which recommendations could have been updated from the 2007 LBD CPG.

Evidence Reviewed*	Recommendation Category*	Definition*
Reviewed	New-added	New recommendation following review of the evidence
	New-replaced	Recommendation from previous CPG that has been carried over to the updated CPG that has been changed following review of the evidence
	Not changed	Recommendation from previous CPG that has been carried forward to the updated CPG where the evidence has been reviewed but the recommendation is not changed
	Amended	Recommendation from the previous CPG that has been carried forward to the updated CPG where the evidence has been reviewed and a minor amendment has been made
	Deleted	Recommendation from the previous CPG that has been removed based on review of the evidence
Not reviewed	Not changed	Recommendation from previous CPG that has been carried forward to the updated CPG, but for which the evidence has not been

Evidence Reviewed*	Recommendation Category*	Definition*
		reviewed
	Amended	Recommendation from the previous CPG that has been carried forward to the updated CPG where the evidence has not been reviewed and a minor amendment has been made
	Deleted	Recommendation from the previous CPG that has been removed because it was deemed out of scope for the updated CPG

*Adapted from the NICE guideline manual (2012) and Garcia et al. (2014).

See Appendix A in the original guideline document for further details on categorization.

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

After developing the initial draft of the updated clinical practice guideline (CPG), an iterative review process was used to solicit feedback on and make revisions to the CPG. Once they were developed, the first two drafts of the CPG were posted on a wiki website for a period of 14 to 20 business days for internal review and comment by the Work Group. All feedback submitted during each review period was reviewed and discussed by the Work Group and appropriate revisions were made to the CPG.

Draft 3 of the CPG was made available for peer review and comment. This process is described in Peer Review Process section in the original guideline document. After revisions were made based on the feedback received during the peer review and comment period, the Champions presented the CPG to the Evidence Based Practice Work Group (EBPWG) for their approval. Changes were made based on feedback from the EBPWG and the guideline was finalized.

The final 2017 LBP CPG was submitted to the EBPWG in September 2017.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

Table A-4 in the original guideline document indicates the number and type of studies that addressed each of the questions. The systematic review (SR) conducted for the update of this clinical practice guideline (CPG) encompassed intervention studies (primarily randomized controlled trials [RCTs]) and observational studies.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

The expected outcome of successful implementation of this guideline is to:

Assess the patient's condition and determine, in collaboration with the patient, the best treatment method
Optimize each individual's health outcomes and improve quality of life
Minimize preventable complications and morbidity
Emphasize the use of patient-centered care

Refer to the "Discussion" sections following each recommendation in the original guideline document for information on the balance between benefits and harms for specific recommendations.

Potential Harms

- The harms of diagnostic testing are the potential false positive red flag symptoms that may cause unnecessary additional diagnostic workup and the inherent risks and increased costs with those modalities, plus the fear or anxiety that may be experienced by the individual when undergoing diagnostic testing.
- Adverse effects associated with duloxetine include nausea, insomnia, dry mouth, constipation, somnolence, and fatigue.
- Muscle relaxants were associated with higher rates of adverse events, such as central nervous system (CNS) effects including sedation, nausea, dizziness, and headache.

Refer to the "Discussion" sections following each recommendation in the original guideline document for information on the balance between benefits and harms for specific recommendations.

Contraindications

Contraindications

- Magnetic resonance imaging (MRI) is contraindicated in patients with pacemakers.
- Duloxetine has a risk of hepatotoxicity and should not be used in individuals with liver disease.
- Caution should be used when prescribing tricyclic antidepressants (TCAs) to individuals with cardiac risk factors, and anticholinergic burden should also be taken into account when used in geriatric patients. In general, TCAs are not recommended in the elderly population.

Qualifying Statements

Qualifying Statements

- The Department of Veterans Affairs and the Department of Defense guidelines are based upon the best information available at the time of publication. They are designed to provide information and assist decision making. They are not intended to define a standard of care and should not be construed as one. Neither should they be interpreted as prescribing an exclusive course of management.
- This clinical practice guideline (CPG) is based on a systematic review of both clinical and epidemiological evidence. Developed by a panel of multidisciplinary experts, it provides a clear explanation of the logical relationships between various care options and health outcomes while rating both the quality of the evidence and the strength of the recommendation.
- Variations in practice will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every healthcare professional making use of these guidelines is responsible for evaluating

the appropriateness of applying them in the setting of any particular clinical situation.

- These guidelines are not intended to represent Department of Veterans Affairs or TRICARE policy. Further, inclusion of recommendations for specific testing and/or therapeutic interventions within these guidelines does not guarantee coverage of civilian sector care. Additional information on current TRICARE benefits may be found at www.tricare.mil or by contacting your regional TRICARE Managed Care Support Contractor.
- As with other CPGs, there are limitations, including significant evidence gaps, and a need to develop effective strategies for guideline implementation and evaluation of the effect of guideline adherence on clinical outcomes. Thus, as stated above, this CPG is not intended to serve as a standard of care. Standards of care are determined on the basis of all clinical data available for an individual patient and are subject to change as scientific knowledge and technology advance and patterns evolve. This CPG is based on evidence available through October 2016 and is intended to provide a general guide to best practices. The guideline can assist healthcare providers, but the use of a CPG must always be considered as a recommendation, within the context of a provider's clinical judgment and patient values and preferences, for the care of an individual patient.

Implementation of the Guideline

Description of Implementation Strategy

This clinical practice guideline (CPG) and algorithm are designed to be adapted by healthcare providers for the treatment of individual patients, bearing in mind patient-level considerations as well as local needs and resources. The algorithm serves as a tool to prompt providers to consider key decision points in the course of care.

Although this CPG represents the recommended practice on the date of its publication, medical practice is evolving and this evolution requires continuous updating based on published information. New technology and more research will improve patient care in the future. Identifying areas where evidence was lacking for the 2017 CPG can help identify priority areas for future research. Future studies examining the results of low back pain (LBP) CPG implementation may lead to the development of new evidence particularly relevant to clinical practice.

Implementation Tools

Clinical Algorithm

Patient Resources

Pocket Guide/Reference Cards

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Diagnosis and Treatment of Low Back Pain Work Group. VA/DoD clinical practice guideline for diagnosis and management of low back pain. Version 2.0. Washington (DC): Department of Veterans Affairs, Department of Defense; 2017 Sep. 110 p. [142 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2017 Sep

Guideline Developer(s)

Department of Defense - Federal Government Agency [U.S.]

Department of Veterans Affairs - Federal Government Agency [U.S.]

Veterans Health Administration - Federal Government Agency [U.S.]

Source(s) of Funding

United States Government

Guideline Committee

Diagnosis and Treatment of Low Back Pain Work Group

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Financial Disclosures/Conflicts of Interest

Conflict of Interest

At the start of this guideline development process and at other key points throughout, the project team was required to submit disclosure statements to reveal any areas of potential conflict of interest (COI) in the past 24 months. Verbal affirmations of no COI were also used as necessary during meetings throughout the guideline development process. The project team was also subject to random web-based surveillance (e.g., ProPublica, Centers for Medicare & Medicaid Services [CMS] Open Payments).

If a project team member reported a COI (actual or potential), then it was reported to the Office of Evidence Based Practice. It was also discussed with the low Back Pain (LBP) Clinical Practice Guideline (CPG) Work Group in tandem with their review of the evidence and development of recommendations. The Office of Evidence Based Practice and the LBP CPG Work Group determined whether or not action, such as restricting participation and/or voting on sections related to the conflict or removal from the Work Group, was necessary. If it was deemed necessary, action to mitigate the COI was taken by the Champions and Office of Evidence Based Practice, based on the level and extent of involvement. No conflicts of interest were identified for the LBP CPG Work Group members or Champions. Disclosure forms are on file with the Department of Veterans Affairs Evidence Based Practice Program office and available upon request.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Veterans Health Administration, Department of Defense. Clinical practice guideline for the management of low back pain or sciatica in the primary care setting. Washington (DC): Department of Veterans Affairs (U.S.); 1999 May. Various p. [216 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

Guideline Availability

Available from the Department of Veterans Affairs (VA) Web site .

Availability of Companion Documents

The following are available:

VA/DoD clinical practice guideline for diagnosis and treatment of low back pain. Version 2.0. Clinician summary. Washington (DC): Department of Veterans Affairs, Department of Defense; 2017 Sep. 35 p. Available from the Department of Veterans Affairs (VA) Web site .

VA/DoD clinical practice guideline for diagnosis and treatment of low back pain. Version 2.0. Pocket card. Washington (DC): Department of Veterans Affairs, Department of Defense; 2017 Sep. 9 p. Available from the VA Web site .

Guideline for guidelines. Washington (DC): Department of Veterans Affairs; 2013 Apr 10. 26 p. Available from the VA Web site .

Putting clinical practice guidelines to work in VHA. Washington (DC): Department of Veterans Affairs. 64 p. Available from the VA Web site .

Patient Resources

The following is available:

VA/DoD clinical practice guideline for diagnosis and treatment of low back pain. Version 2.0. Patient summary. Washington (DC): Department of Veterans Affairs, Department of Defense; 2017 Sep. 4 p. Available from the Department of Veterans Affairs (VA) Web site .

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC Status

This NGC summary was completed by ECRI on May 1, 2001. The information was verified by the guideline developer on November 1, 2001. This summary was updated by ECRI Institute on February 13, 2018. The updated information was verified by the guideline developer on February 26, 2018.

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